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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/080,943

02/22/2002

Loren J. Field

7037-458

6536

7590

06/02/2005

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/080,943

Applicant(s)

FIELD ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-17,23-27,34 and 37-50 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 37-43 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23 is/are allowed.
- 6) ☒ Claim(s) 11-17,24-27 and 44-50 is/are rejected.
- 7) ☒ Claim(s) 40 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application filed February 22, 2002, is a continuation of PCT/US00/23161 with the international filing date of August 23, 2000, which claims benefit to US provisional application 60/150,266 filed August 23, 1999.

Applicants amendment filed March 2, 2005 has been received and entered. The specification has been amended. Claims 1-10, 18-22, 28-33, 35-36 have been canceled. Claims 11, 13-17, 23, 24, 34, 37-40 have been amended. Claims 41-50 have been added.

Claims 11-17, 23-27, 34, 37-50 are pending.

### ***Election/Restrictions***

Applicant's election of Group VII, claims 15-17, in the reply filed on June 4, 2004 was acknowledged. In the first action, the Examiner determined it would not be an undue burden to examine both groups VI and V, and the restriction requirement between groups V and VI was withdrawn.

Newly added claims 44-50 are drawn to the elected invention and will be examined. Newly added claims 41-43 are dependent on claims of non-elected inventions, and are withdrawn as being drawn to non-elected inventions. As noted in the first office action, Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement of each of the different inventions, the election has been treated as an election without traverse (MPEP § 818.03(a)).

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Further, as noted in the previous office action, the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting

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rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Claims 11-17, 23-27, 34, 37-50 are pending. Claims 18-22, 28-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 11-17, 23-27, 44-50 are currently under examination as they are drawn to a vector encoding p193 and a host cell comprising a vector.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

The nucleotide sequence disclosure contained in this application complies with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

The amendments to the specification and the filing of the appropriate materials, filed March 2, 2005, has put the application into sequence compliance. See also Applicants' amendment page 7 and paper entered by STIC March 8, 2005.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-17, 24-27 stand rejected and newly added claims 44-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants summarize the basis of the rejection and note the amendments to the claims to address the issue of the recitation of the term “p193 protein” (page 7). Further, it is argued that the percent identity is discussed in the instant specification (on pages 12-13) and that this demonstrates that the written description requirement has been met by the instant disclosure (page 8). See Applicants amendment, bridging pages 7-8. Applicants arguments have been fully considered, but not found persuasive.

Initially, it is noted that claims 23 has been amended to encompass only SEQ ID NOs: 2 or 4. The claim as it is drawn to each of these specific SEQ ID NOs meet the requirements of 35 USC 112, first paragraph, and the rejection is withdrawn with respect to this amended claim. With respect to the remaining claims and newly added claims as they are drawn to and encompass the breadth of sequences that are limited by function or percent identity to SEQ ID NO: 2 or 4, Applicants arguments are not found persuasive because a simple recitation of identity or function is not sufficient description of the specific sequences claimed to meet the requirement of 35 USC 112, first paragraph. The amendments to the claims and the teachings of the specification are noted, however the number of sequences that share 70% identity are enormous compared to the single two separate species of SEQ ID NO; 2 and 4 disclosed.

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Further, there is no detailed description nor disclosure of the necessary sequences that provide the function, pro-apoptotic properties, of even the specific SEQ ID NOs. The specification does teach the isolation and characterization of two specific sequences that encodes a protein that has a molecular weight of 193 kDa, however the specification fails to provide any clear guidance to any other sequences encompassed by the claim. Moreover, the guidelines for written description set forth that both a structure and function must be provided to address the requirement of 35 USC 112, first paragraph. Even when a function is recited, as in dependent claim 17 for example, the claimed invention as a whole is not adequately described because the disclosure fails to teach the essential or critical elements of the claimed invention, in particular the sequences other than SEQ ID NOs that have any apoptotic function. Moreover, there are no specific methods set forth in the present disclosure for obtaining such a breadth of sequences. As note in the prior office action, Applicants have claimed a nucleic acid sequence encoding a p193 protein, however the specification fails to describe the relevant identifying characteristics of any of the nucleic acid sequences of a sufficient number of sequences which can be used in the instantly claimed method. The skilled artisan cannot envision all the possible variant nucleic acid sequences encompassed by the claims, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method used. Again, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Therefore, for the reasons above and of record, the rejection is maintained.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-17 and 23-27 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

The amendments to the claims and Applicants' arguments have addressed the rejections of record.

### ***Conclusion***

Claim 23 is allowed because the prior art of record fails to teach or make obvious the specific sequences of SEQ ID NO: 2 or 4. As noted previously all of the claims are free of the art of record because the art fails to teach an isolated nucleic acid sequence encoding a p193 protein, and more specifically that set forth in SEQ ID NOs: 2-4. Further, the post filing art of Pasumarthi *et al.* and of Tsai *et al.* demonstrate that the function of the p193 protein is in the apoptotic pathway consistent with that disclosed in the instant specification. Though free of the art of record, the remaining claims are subject to other rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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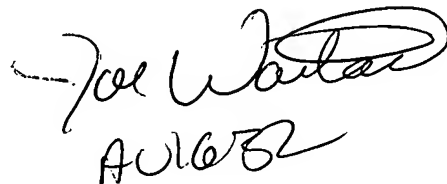
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach



Joe Woitach  
AUL632